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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,889	10/20/2000	Yair Feld	00/20989	7655

7590                    03/28/2002

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EXAMINER

BAKER, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 03/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/691,889	FELD ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Anne Baker	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-37 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input checked="" type="checkbox"/> Other: <i>detailed action</i> .       |

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## DETAILED ACTION

Claims 1-37 are pending in the instant application.

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 5-22, drawn to a nucleic acid construct, a transformed cell, a pharmaceutical composition comprising the nucleic acid construct, classified in class 536, subclass 23.5.
- II. Claims 2-4 and 16, drawn to a tissue explant, classified in class 435, subclass 1.1.
- III. Claims 23-37, drawn to a method of modifying the electrophysiological function of an excitable tissue region of an individual by transplanting cells, either genetically modified cells or unmodified cells, classified in class 424, subclass 93.1.

Claims 2, 3, and 16 embrace the inventions of Groups I and II. Should either of Groups I or 2 be elected, Claim 2, 3, and 16 will be examined only to the extent that they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the inventions are drawn to materially different compositions. The compositions of the invention of Group I (nucleic acids, cells, and pharmaceutical

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compositions) are structurally, chemically, biologically, and functionally distinct from the tissue explant of the invention of Group II. Thus, the compositions of the invention of Group I are patentably distinct from the compositions of the invention of Group II.

Inventions I and III are patentably distinct because the inventions are drawn to distinct compositions and methods. Although the cells of the invention of Group I can be used to practice the method of the invention of Group III, the cells are not limited to this use, as they can also be used for *in vitro* assays. Furthermore, the method of the invention of Group III does not require the cells of the invention of Group I, as unmodified cells can also be used to practice the method of the invention of Group III. Additionally, the pharmaceutical composition of the invention of Group I is not required for practice of the method of the invention of Group III, as the method of the invention of Group III can be practiced using genetically modified cells or unmodified cells. Thus, the compositions of the invention of Group I are patentably distinct from the methods of the invention of Group III.

Inventions II and III are patentably distinct because the inventions are drawn to distinct compositions and methods that are not claimed as being used together. Although the tissue explant of the invention of Group II could be used to practice the method of the invention of Group III, the tissue is not limited to this use, as it can also be used for *in vitro* assays. Furthermore, the tissue explant of the invention of Group II is not required for practice of the method of the invention of Group III, as the method of the invention of Group III can be practiced using genetically modified cells or unmodified cells. Thus, the composition of the invention of Group II is patentably distinct from the method of the invention of Group III.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.

*Anne-Marie Baker*  
ANNE-MARIE BAKER  
PATENT EXAMINER